REMARKS

Claims 3, 11, 12, 13, 14, 17, 18, 19, 20, 22, 30, 31, 32, 34, 35, 36, 44, 47, 48, and 49 have been cancelled. Claims 37-39 and 40-43 have been amended. New claims 50-57 have been added. Claims 1, 2, 4-10, 15-16, 21, 23-29, 37-43, and 50-57 are now pending in the application. No new matter has been added by amendment. Reexamination and reconsideration of the claims as amended are respectfully requested.

Claim Rejections – 35 USC § 112, second paragraph

The Examiner rejects claims 3, 11-13, 18-20, 22, 30-32, and 47-49 under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant traverses the rejection.

The Examiner rejects claims 3 and 22. Claims 3 and 22 have been cancelled.

The Examiner rejects claims 11 and 30, and dependent claims 12-13 and 31-32. Claims 11, 12, 13, 30, 31, and 32 have been cancelled.

The Examiner rejects claims 18 and 47, and dependent claims 19-20 and 48-49. Claims 18, 19, 20, 47, 48, and 49 have been cancelled.

The Examiner states that the dependent claims cited in this rejection fail to further limit the claims from which they depend. The Examiner suggests that the claims be placed in a product –by-process format. New claims 50-57 reflect that suggestion. The Examiner also suggests that the claims should be drafted in terms of methods of making a plant by comprising transforming the exemplified plant of claim 2 or 21. New claims 54-57 reflect that suggestion.

Claim Rejections – 35 USC § 112, first paragraph

The Examiner rejects claims 3, 9-20, 22, 28-32, 34-44 and 47-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Applicant traverses the rejection. Claims 3, 11, 12, 13, 14, 17, 18, 19, 20, 22, 30, 31, 32, 34, 35, 36, 44, 47, 48, and 49 have been cancelled. Claims 37, 38, 39, 40, 41, 42, and 43 have been amended. New claims 50-57 have been added.

The Examiner rejects claims 11, 15-16, 30, 34-35 and their dependent claims and states that the claims "are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of making and using the transgenic plants." The Examiner rejects claims 3, 18-20, 22, and 47-49 and their dependent claims and states that the claims "are broadly drawn to any 'single gene conversion' plant comprising one or more traits including male sterility introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants." The Examiner states that "no guidance has been provided for the introgression of any single trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement." The Examiner also states that claims are "broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of making or using the transgenic plants." The Examiner states that, "No guidance has been provided for the description or characterization of a multitude of heterologous coding sequences conferring a multitude of traits."

Claims 3, 11, 12, 13, 18, 19, 20, 22, 30, 31, 32, 47, 48, and 49 have been cancelled to place the claims in the method and product by method format requested by the Examiner. New claims 50, 52 54 and 56 are drawn to

methods, while their depending claims are drawn to the products produced by those methods. The claims include the well known methods of producing backcross and transgenic conversion plants. The product by process claims are further limited by specified conversion or transgenic traits, which include the traits of insect resistance, herbicide resistance, disease resistance and male sterility.

While the Examiner states that the claims encompass "any transgenic plant which contains any heterologous transgene of any sequence conferring any trait", the Applicant points out that it is not claiming so broadly as to claim any maize plant, regardless of source, comprising those traits. The Applicant is claiming PH726 or a limited set of plants derived therefrom that have obtained significant genetic contribution from PH726.

Applicant has made an enabling deposit of PH726 with the ATCC, and the Applicant is seeking a fair scope of protection as the quid pro quo for the teaching in the specification and the deposit of the material. The introgression of one or a few genes into a genome that is estimated to have over 50,000 to 80,000 genes (Xiaowu, Gai et al., Nucleic Acids Research, 2000, Vol. 28, No. 1, 94-96) is a minor change to PH726 and will not prevent one of skill in the art from identifying the plant as being derived from PH726.

Applicant respectfully points out that examples of transgenes, genes, and traits that can be backcrossed into the PH726 are given in the application on page 21, lines 16-34, and also on page 23, line 20, through page 33, line 4. In order to expedite prosecution new claims 51 and 55 list the type of traits that may be conferred by backcross conversions and transgenes. Claim 51 also specifies that PH726 is used at least twice as a recurrent parent in the development of a backcross conversion plant. Breeders, by using molecular markers, may obtain up to 98% genome identity between the backcross conversion and the recurrent parent after two backcrosses. See Marker-assisted Selection in Backcross Breeding, Openshaw, S.J. et al. Marker-assisted selection in backcross breeding. In: Proceedings Symposium of the Analysis of Molecular Data, 5-6 August 1994, pp. 41-43. Crop Science Society of America,

Corvallis, OR (1994) included as Appendix A. Inbred PH726 transformed to comprise a transgene is also easily identifiable through the use of molecular markers. The transgenic version of PH726 would have the same molecular profile as PH726, with the possible exception of a marker used in the profile that is located at the site of transgene insertion. However, in this case, the plethora of other identical markers would identify the line as a transgenic variant of PH726.

Applicant points out to the Examiner that, at the present time, it is not typical that a transgene be incorporated into each newly developed line, such as PH726, by direct transformation. Rather, the more typical method used by breeders of ordinary skill in the art is to incorporate the transgene into a new line by taking an already transformed plant line and using it as a donor line to produce a backcross conversion. Thus, the well established method of backcrossing has been used and is the most common means of introgressing the claimed traits into new material.

In the specification on page 4, lines 7-13, it states, "Backcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. This can be accomplished, for example, by first crossing a superior inbred (recurrent parent) to a donor inbred (non-recurrent parent), that carries the appropriate gene(s) for the trait in question. The progeny of this cross is then mated back to the superior recurrent parent followed by selection in the resultant progeny for the desired trait to be transferred from the non-recurrent parent." The method of backcrossing genes into an inbred maize plant is well known and well understood to one of ordinary skill in the art. The method has been successfully used since the 1950's (see pages 585-586 of Wych, 1988 included in the Information Disclosure Statement). In the specification, on page 21, lines 16-34, there is a description of how to backcross traits into PH726, which includes the claimed traits. Examples of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion

lines are easily developed without undue experimentation. Poehlman et al. (1995) on page 334, submitted in the information disclosure statement, states that, "A backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." Wych (1988) on page 585-86, also submitted in the information disclosure statement, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile (backcross conversion) inbred to be the same variety as the F1 hybrid produced with the non-backcross conversion inbred.

As a result of the repeated use of the recurrent parent, the backcross conversion has many genetic alleles in common with the recurrent parent. Thus, genetic analysis may be used as a means of identifying the backcross conversion. The declaration attached as Appendix B explains how genetic analysis was used to identify backcross conversion inbreds of PH726. The F1 hybrid made with a transgenic version or a backcross conversion of PH726 is also identifiable by the use of genetic markers, because the hybrid would contain one set of alleles from each parent. The Examiner also states that the Applicant has not characterized parentals. Applicant respectfully disagrees. In a backcross conversion the deposited material is repeatedly used as the parental line.

The Examiner rejects claims 9-10, 12-17, 28-32, and 34-44 and states that the claims "are also broadly drawn to any plant produced by crossing the exemplified with any of a multitude of non-exemplified plants, or any descendents of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners."

The Examiner rejects claims 9, 10, 28, and 29, that claim the F1 hybrid seed and F1 hybrid plant made with PH726 as a parent. Applicant notes that a

claim to the F1 hybrid made with a deposited inbred was expressly acknowledged without reservation by the United States Supreme Court In *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 60 USPQ 2d 1865,1873 (S.Ct. 2001), when the Supreme Court wrote, "...a utility patent on an inbred plant line protects the line as well as all hybrids produced by crossing that inbred with another plant line." Further, one of ordinary skill in the art would know how to cross PH726 with another maize plant. The F1 hybrid seed and plant produced using PH726, regardless of the other maize plant used, is identifiable because it will have one set of alleles coming from PH726. One of ordinary skill in the art would be able to run a molecular profile on PH726 and the F1 hybrid and be able to identify the F1 hybrid as being produced from PH726. Seed pericarp tissue, which is solely maternal in origin, can be used to discern the maternal or paternal origin of the allele sets if necessary. See page 16 of Poethig, R.S. 1982. Maize, the plant and its parts. In: W.F. Sheridan (Ed.) Maize for Biological Research, University of North Dakota Press, Grand Forks, ND. pp. 9-18, submitted as Appendix C.

As stated in the specification on page 16, lines 8-23, there are many laboratory-based techniques available for the analysis comparison and characterization of plant genotype such as Restriction Length Polymorphisms (RFLPs) and Simple Sequence Repeats (SSRs). Such techniques may be used to identify whether or not PH726 was used to develop a hybrid. The Applicant also submits to the Examiner the journal article by Berry et al. (2002). This article discusses the probability of identifying the parents of the hybrid by SSR data when neither parent is known and without the use of pericarp analysis. A copy of the article by Berry et al. is attached to this Amendment and Request for Reconsideration as Appendix D. The results of the experiment showed that using 100 SSR loci markers resulted in correct parental ranking of inbreds for 53 out of 54 hybrids. Applicant also points out that any breeder of ordinary skill in the art will know the identity of both parents used to produce a hybrid.

The Examiner rejects claims 12-17, 30-32, and 33-44. Claims 12-14, 30-32, 34-36, and 44 have been cancelled. Claims 15, 16, 28, and 29 remain

pending and are to methods of developing a maize plant through the utilization of PH726. Applicant points out that anyone of skill in the art would know how to utilize the well established breeding methods with PH726. Description of such occurs throughout the specification and descriptions can also be found in introductory plant breeding books. Claims 40-43 remain pending and have been amended. Claim 40 is to the method of producing a first generation PH726-derived hybrid maize plant. Applicant believes the patent office has previously indicated this claim scope as allowable and requests that this rejection be withdrawn. Claim 41 is to the first generation PH726-derived hybrid maize plant produced by the method of claim 40. The first generation hybrid, or F1 hybrid, is identifiable through both breeding records and molecular marker techniques as discussed above. Claim 42 is to the method of selfing the first generation hybrid PH726 for successive filial generations. This is a basic and well known breeding methodology, and the use of this methodology with PH726 is described in the specification on page 21, lines 1 to 15.

Claim 43 is to plants derived from claim 42 that have at least 50% of their genetics derived from PH726. These claimed plants are clearly described by their method of production, which requires the use of PH726. Such plants must be produced through the use of PH726 and the Examiner acknowledges that PH726 is clearly identified. Further, Applicant has added the limitation of at least 50% inheritance from the PH726 side of its pedigree to further emphasize the significant influence of PH726 in the claimed product. Genetic inheritance has been accepted by both courts and governmental agencies as an accurate and reliable means of identification. In paternity cases courts routinely compel genetic testing of putative fathers to establish paternity, and federal law mandates that states have laws requiring that genetic test results be admissible in such cases without the necessity for foundation testimony or other proof. 42 U.S.C. 666(a)(5)(F)(iii)(Supp. V 1999). In such cases, a child will, on average, inherit 50% genetic contribution from each parent. Similarly, the plants produced by the method of claim 42 will also, on average, inherit 50% genetic contribution from each parent.

Applicant requests that the Examiner examine the sufficiency of description of claim 43 with all of its claim limitations, including the limitation that the progeny be produced by the method of claim 42, with the use of PH726 and retaining at least 50% genetic contribution from PH726. One of ordinary skill in the art would know how to cross PH726 to develop an F1 hybrid and also how to self plants derived from the cross with PH726. In *Ex parte Parks*, 30 USPQ 2d 1234 (B.P.A.I. 1994), the Board of Appeals stated, "Adequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention. Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." Emphasis added. In *J.E.M. Ag. Supply*, the Supreme Court also acknowledged the value of a newly developed line in further breeding, when it stated that, "...a breeder can use a plant that is protected by PVP certificate to 'develop' a new inbred line while he cannot use a plant patented under §101 for such a purpose." Id. at 1873.

The Examiner cites the Federal Circuit as stating that the written description of an invention "requires precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co:, 119 F. 3d 1559, 1568; 43USPQ2d 1398, 1406 (Fed. Cir. 1997). The Applicant has fulfilled this written description requirement through the seed deposit of PH726. As described in the specification, lines 8-23 on page 16, the seed deposit allows one of ordinary skill to run a molecular profile of PH726. Applicant submits the molecular profile of inbred line PH726 in the declaration of Dinakar Bhattramakki attached hereto as Appendix E. Further Applicant amends the specification to include such SSR profile. Such SSR profile is not new matter, as it is an inherent feature of inbred line PH726, a representative sample of which has been deposited with the ATCC. For example, see Ex parte Marsili, Rosetti, and Pasqualucci, 214 USPQ 904 (1972), in which the Patent and Trademark Office Board of Appeals held that it was not new matter to amend the structure of a compound when a more refined analytic investigation showed a corrected

formula. The Board, relying on well established cases of In re Nathan et al, 51 CCPA 1059, 328 F.2d 1005, 140 USPQ 601 (1964); In re Sulkowski, 487 F.2d 920, 180 USPQ 46 (CCPA 1973); Spero v. Ringold, 54 CCPA 1407, 377 F.2d. 652, 153 USPQ 726 (1967), and Petisi et al. v. Rennhard et al., 53 CCPA 1452, 363 F. 2d 903, 150 USPQ 669 (1966) concluded that the "products described, exemplified and claimed by Appellants inherently had and have now the structure given in the amendment in question. Consequently, the changes made in this amendment do not constitute new matter. Marsili at 906. Similarly, in the present case, inbred line PH726 inherently had and still has the SSR marker profile being added. One of ordinary skill in the art can use molecular markers to identify PH726, a transgenic version of PH726, a backcross conversion of PH726 and the F1 plant of the transgenic version and backcross conversion of PH726.

The Applicant would also like to point out that the specification also identifies PH726 with phenotypic descriptions. Various examples of breeding methods, transgenes, transformation procedures, and F1 hybrid production are given in the specification. The mean values of traits for numerous F1 plants, wherein PH726 is the parent and other numerous maize plants are the second parent, are given in Tables 3A-3C, pages 44-46. Table 4 contains mean values of traits to a specific F1 wherein PH726 is a parent.

The Examiner also stated, in reference to Lilly, that, "the court also concluded that 'naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Id." This is not the case here. Applicant has created a novel line and seeks a scope of protection that adequately protects the invention. Applicant believes that the derivatives, variants and closely related progeny easily and routinely created by use of this newly developed line are encompassed within the scope of the invention of the variety itself. These derivatives, variants and closely related progeny derive direct and substantial benefit from Applicant's work and deserve to be included within the scope of the claims. Thus, the issue here is patent scope around what has already been

created (and deposited) by Applicant. The fact that the progeny have not been created does not prevent them from being protected in this manner. As stated in MPEP 2163 (3) (a), "An invention may be complete and ready for patenting before it has actually been reduced to practice."

In Enzo vs. Gen-Probe, U.S. State Court of Appeals for the Federal Circuit, 63 USPQ 2d 1609, the court reversed its prior decision regarding the insufficiency of the deposited genetic probes to meet the written description requirement. In so holding, the court stated, " As the deposited sequences are about 850, 8500, and 1300 nucleotides long, ..., there are at least hundreds of subsequences of the deposited sequences, an unknown number of which might also meet the claimed hybridization ratio. Moreover, Enzo's expert, Dr. Wetmur, stated that 'astronomical' numbers of mutated variations of the deposited sequence also fall within the scope of those claims, and that such broad claim scope is necessary to adequately protect Enzo's invention from copyists who could otherwise make minor change to the sequence and thereby avoid infringement while still exploiting the benefits of Enzo's invention. The defendants assert that such breadth is fatal to the adequacy of the written description. On the other hand, because the deposited sequences are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art. We regard that question as an issue of fact...."

The issue of whether the progeny as now claimed satisfies the written description requirement is also an issue of fact. PH726 is a unique inbred, as evidenced by the morphological and physiological traits given in Table 1, pages 18-20, of the application. Routinely used molecular techniques, discussed on page 16, lines 8-23 of the application, can be used to verify whether PH726 is within the pedigree of a claimed plant. One of ordinary skill in the art would also know from breeding records if PH726 were utilized in the development of a claimed plant.

As stated in the written description guidelines "an applicant shows possession of the claimed invention by describing the claimed invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways, including...by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention." 1255 Official Gazette 140 (Feb. 5, 2002). Phenotypic traits are used in the text of the specification. Genetic and other molecular profiles may be obtained from the deposit. Once a line is identified as being PH726, one of ordinary skill in the art would also easily be able to determine which progeny they develop from that line fall within the scope of the claims.

Within the plant breeding arts breeders use pedigree as a means to characterize lines in reference to their progenitors. It is unambiguous and easily traceable through breeding records that are maintained by any breeder of ordinary skill in the art. It indicates that a line fewer crosses away from a starting line will be, as a whole, more highly related to the starting line. Thus, the work of the original breeder in developing the starting line will be retained in the closely related progeny. More specifically, traits and linkage groups present in PH726 will be retained in progeny that are within one outcross from PH726. Applicant submits that characterization of the progeny of PH726 by virtue of their filial relationship is a clear and acceptable means of identification. Not only are filial descriptions used by breeders to evaluate materials for use in their breeding programs, but it is standard practice within the plant breeding industry for universities and companies that license inbred maize lines to retain a royalty from lines developed through the use of their inbreds. Those royalties are, in almost all cases, based on the filial relationship between the licensed inbred used in breeding and the progeny line commercialized. This is further evidence that those of ordinary skill in the art of plant breeding describe progeny in terms of pedigree and find it an acceptable means of characterization.

As noted in the specification, the development of an inbred line is a time consuming and labor intensive activity. On average, between 10,000 to 20,000

lines are created and screened in order to develop any maize inbred line for which the Applicant files a patent application. Once developed, the inbred line is useful for two purposes: (1) to make commercial hybrids, and (2) as a source of breeding material for the development of new inbreds that retain the original inbred's desired characteristics. A breeder desiring to make a line with similar traits to PH726 would be greatly advantaged by being able to use PH726 as starting material. This is because the linked genes arranged through Applicant's breeding efforts, and fixed in PH726, can be maintained in the progeny of PH726 by a breeder of ordinary skill in the art. The end result is the development of an inbred line with substantial benefit from the Applicant's work.

PH726-derived progeny are described by the fact that PH726 is utilized in a breeding program to make the PH726-derived progeny, PH726 gives genetic contribution to the PH726-derived progeny, and the genetics of PH726 are described by ATCC deposit of PH726 seed. By limiting the progeny to one outcross away from PH726 and by limiting the progeny to those that contain at least 50% of their genetics from PH726, the Examiner's concern that the progeny may be only distantly related to PH726 is addressed.

Applicant would also like to emphasize that PH726 cannot be derived through any other means than through PH726 seed and plant, nor can the influence of PH726 on the progeny be removed from a line within one outcross of PH726. To view this claim as one of breadth ignores an essential limitation of the claim; that only a plant developed through the use of PH726 is within the scope of the claim. Such a plant could not be obtained without the use of PH726, so the claim would not in any way restrict the work of a breeder that did not in fact use PH726. Compliance with the written description requirement is essentially a fact based inquiry that will "necessarily vary depending on the nature of the invention claimed." Vas-Cath v. Mahurkar, 935 F. 2d 1555 (citing In re DiLeone, 436 F2d. 1404, 1405). Thus, the compliance with the written description requirement must be judged in view of this limited scope of the progeny claims. As amended, the claims are drawn to only a limited scope of progeny, progeny whose existence is the direct result of the use of PH726. This

is in harmony with the statement in section 2163 of the MPEP that "the written description requirement promotes the progress of the useful arts by ensuring inventions are adequately described in the specification in exchange for the right to exclude." That quid pro quo of patent law has been met by the Applicant in the present case, and to use written description to deny adequate patent protection would be contrary to the stated purpose of the written description requirement.

The Examiner also rejects claims 37-39 under 35 USC § 112, first paragraph. Claims 37-39 have been amended for clarification purposes. Claims 37-39 are directed to growing out an F1 hybrid in which PH726 is a parent and searching for PH726 inbred seed. Due to the imperfect process of seed production parent seed can sometimes be contained in the hybrid seed bag. This claim covers the method of searching for inbred PH726 seed within a bag of hybrid seed. The method is clearly described in the specification on page 5, line 21 through line 7 on page 6. One of ordinary skill in the art can practice such a method without undue experimentation. The Applicant requests that the Examiner withdraw his rejection to claims 37-39.

The Examiner rejects claims 3, 9-20, 22, 28-32, 34-44, and 47-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant traverses the rejection.

With the exception of the arguments pertaining to Hunsperger et. al., Kraft et. al. and Eshed et. al., the Examiner provides nearly identical arguments for the 112, first paragraph, lack of enablement rejection as those provided for the 112, first paragraph, lack of written description rejection addressed above.

To avoid repetition, Applicant respectfully requests that the Examiner consider the arguments made in response to the 112, first paragraph, lack of written description rejection as also applicable to the 112, first paragraph, lack of

enablement rejection. In addition, the Applicant directly addresses the arguments raised by the Examiner that relate to Hunsperger, Kraft and Eshed.

The Examiner has cited Hunsperger, Kraft and Eshed and stated that they "teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant." The Examiner states that, "Hunsperger et al teach that the introgession of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46)." Applicant's respectfully disagree that this is what is taught by Hunsperger et al. Hunsperger et al. teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger et al. merely discusses the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger et al. succeeded in incorporating the gene into petunia plants of different genetic backgrounds. Therefore, Hunsperger et al. support the fact that one can introgress a specific trait into a recurrent parent through backcross conversion. Applicant's specification provides ample disclosure of starting materials such as maize inbred PH726, a discussion of traditional breeding methods, and examples of transgenes and naturally occurring genes that may be used in such methods. Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, state that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." The teaching of Hallauer relates specifically to corn breeding and corn inbred line development, while Hunsperger et al relates to petunia.

The Examiner goes on to state that, "Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotypic specific and loci-dependent in nature (see, e.g., page 323)." Applicant disagrees

that the article states such points. Kraft et al. make no mention of a plant comprising a single gene conversion. Further, Kraft et al. relates to linkage disequilibrium and fingerprinting in sugar beet, a crop other than maize. Kraft et al. state, on p. 326, first column, "The generality of our results for other crop species needs to be investigated."

It is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on it's web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering. The commercialization of an essentially derived variety needs the authorization of the owner on the rights vested in the initial variety." International Convention for the Protection of New Varieties of Plants, as amended on March 19, 1991, Chapter V, Article 14, Section 5(c), (emphasis added). A copy of the relevant portion of the UPOV Convention and the World Seed Organization web site is attached as Appendix F.

An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation. Poehlman et al. (1995) on page 334, submitted in the information disclosure statement, states that, "A backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross."

The Examiner goes on to state that, "Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may effect quantitative traits in genetically

complex and less than additive fashion (see, e.g., page 1815). The Applicant would like to point out on page 1816, column 1, lines 1-5 of the Eshed et al. article it states, "Recent studies that detected epistasis of selected QTL in Drosophila (Long et al. 1995), soybean (Lark et al.1995) and maize (Doebley et al.1995; Cockerham and Zeng 1996) did not show a less-than-additive trend." Emphasis added. Applicant also adds that transferring a qualitative trait does not require undue experimentation. Please note Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." Claim 51 has been amended to expedite prosecution. In claim 51, the genes transferred into PH726 are now limited to the traits of herbicide resistance, insect resistance, disease resistance, male sterility, and waxy starch.

The Examiner alleges that Applicant's traversal of the art rejection on pages 7-8 of the amendment of 22 August 2002 "admits that outcrossing the exemplified inbred to another undisclosed plant is unpredictable." Applicant's statements on pages 7-8 of the amendment of 22 August 2002 make the point that it is not possible to use the cited prior art line F361 to produce a line that is the same as PH726 or any of the claimed progeny of PH726. Applicant did not in any way state that it would be unpredictable to introgress a gene into PH726 through backcross breeding techniques or transformation.

In light of the amendments to the claims and the foregoing arguments the Applicant requests reconsideration of the rejection under the first paragraph of 35 U.S.C. 112.

Claim Rejections under 35 U.S.C. § 102 and 103

The Examiner states that, "Claims 14 and 43 remain rejected under 35 U.S.C. 102(b) as anticipated by or in the alternative, under 35 U.S.C. 103(a) as obvious over Morgan (U.S. Patent No. 5,824,848)." Applicant traverses the rejection.

Applicant has cancelled claim 14. Applicant has amended claim 43. Claim 43 is limited to progeny produced by the method of claim 42, which requires the use of PH726, and is further limited to progeny deriving at least 50% genetic contribution from PH726.

The Examiner has made several objections which relate to written description and these were addressed in the response to the written description section above. The Examiner then makes the statement that "It is unclear and unlikely that the genetic material that remains in the first generation progeny retain the unique genetic and morphological complement of the exemplified inbred...Furthermore, since the *individual* traits exhibited by the exemplified inbred are not unique to the exemplified inbred, either by degree of expression nor genetic means of inheritance, a descendent of the exemplified inbred containing no genetic material from it could still exhibit these individual traits, and could still possess the same genetic means for conferring these traits as did the exemplified inbred."

Applicant responds that such a described inbred is not within the scope of the claim as amended, because it would not have at least 50% genetic contribution from PH726. Further, the benefit of the invention relates not to plants comprising these traits in general, but plants that comprise these traits through the use of PH726 and the work of Applicant in fixing these traits and linkage groups in PH726. Nothing in claim 43 would restrict a breeder from making, using or selling a line with all of the same morphological and physiological characteristics of PH726 or the plant of claim 43, so long as such plant was created without the use of PH726.

Further, as evidenced by the declaration of Stephen Smith submitted as Appendix G, both PH726 and its progeny within the scope of claim 43 are distinct from F361 taught in U.S. Patent No. 5,824,848.

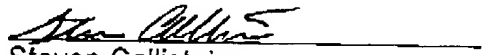
In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection to claims 1-49 under 35 U.S.C. 102 (b) and 103(a).

Claims 1, 2, 4-10, 15-16, 21, 23-29, 37-43, and 50-57 are now pending in the application. The amendments made herein do not in any way change the claim scope which the Applicant believes is allowable but is meant to hasten the issuance of the patent.

CONCLUSION

Applicant submits that in light of the foregoing amendments and the remarks, the claims 1, 2, 4-10, 15-16, 21, 23-29, 37-43, and 50-57 are in condition for allowance. Reconsideration and early notice of allowability is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Respectfully submitted,
Joseph Kevin Gogerty



Steven Callistein
Reg. No. 43,525
Attorney for Applicant

Steven Callistein
Pioneer Hi-Bred International
7100 NW 62nd Avenue
P.O. Box 1000
Johnston, IA 50131-1000
(515) 254-2823
(515) 224-6883 Facsimile